JUN 2 5 2001

K011383

ATTACHMENT D: 510(K) SUMMARY

General Information

Classification	Class II
Trade Name	IntraEAR® Microdose Cath ™
Submitter	Durect Corporation 10240 Bubb Road Cupertino, CA 95014 408-864-7409
Contact	Jeff P. Miller Executive Director, Regulatory Affairs & Compliance

Intended Use

The Microdose Cath is indicated as a temporary (less than 29 days) indwelling catheter for delivery of fluids to the middle ear including the round window area of the middle ear in the treatment of patients with ear disorders.

Predicate Devices

K965115 IntraEAR RwμCath™

Device Description

The Microdose Cath is a small diameter bi-lumen catheter with a round molded distal tip which has holes that allow fluid to escape. The product has a proximal septum to allow fluid infusion with a standard syringe and needle. The product length enables fluid delivery to be completely contained within the ear.

Materials

The catheter is molded of biocompatible materials and is supplied sterile. It is intended for single use only.

All materials used in the manufacture of the Microdose Cath are suitable for this use and have been used in numerous previously cleared products.

Testing

Product testing was conducted to evaluate conformance to product specification. Testing included bond strength, septum access, fluid flow, dimensional tolerances, leak and fluid volume. The product met these specifications.

Summary of Substantial Equivalence

The Microdose Cath is equivalent to the predicate products. The indications for use, basic overall function, methods of manufacturing, and materials used are substantially equivalent. Durect Corporation believes the Microdose Cath is substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 5 2001

Durect Corporation
c/o Mr. Jeff P. Miller
Executive Director,
Regulatory Affairs & Compliance
10240 Bubb Road
Cupertino, CA 95014

Re: K011383
Trade Name: IntraEAR® Microdose Cath™
Regulation Name: 874.3880
Regulatory Class: II
Product Code: 77 ETD
Dated: May 31, 2001
Received: June 1, 2001

Dear Mr. Miller:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K011383

1.0 Indications for Use

510(k) Number (if known): (Pending assignment number)

Device Name: IntraEAR® Microdose Cath™

Indications for Use: The indications for use are the same as the predicate.

The IntraEAR® Microdose Cath™ (hereafter, Microdose Cath) is indicated as a temporary (less than 29 days) indwelling catheter for delivery of fluids to the middle ear including the round window area of the middle ear in the treatment of patients with ear disorders.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K011383